K090250

510(k) SUMMARY

For

Hill Laboratories

Electro-Light Therapy

FEB 11 2010

1. Submitter's Name and Address

Submitter's Name:	Hill Laboratories
Address:	3 Bacton Hill Rd
City, State, and Zip:	Frazer, PA 19355

2. Contact Person

Name:	Brady Aller
Title:	Sales/Service Manager
Telephone:	(610) 644-2867
Facsimile:	(610) 647-6297
E-mail:	bradyaller@hilllabs.com

3, Manufacturing Facility Address

Manufacturer:	Hill Laboratories
Address:	3 Bacton Hill Rd
City, State, and ZIP:	Frazer, PA 19355

4. Establishment Registration Number

Establishment Registration Number: 2510425

5. Reason for Submission

Reason for Submission: New Device

6. Date of Summary Preparation

Date of Summary Preparation: January 26, 2009

7. Device Details

Proprietary or Trade Name:	Electro-Light Therapy
Common Name:	Infrared lamp

8. Device Common Name, Classification, Product Code & CFR No.

Common Name	Class	ProCode	CFR
Infrared lamp	2	ILY	890.5500

9. Classification Name

lamp, infrared, therapeutic heating

10. Device Classification Panel

Physical Medicine

11. Indications for Use

Electro-Light Therapy System is used to provide topical heating for:

- Temporary increases in local blood flow and circulation
- Temporary relief of minor muscle and joint aches
- Temporary relief of pain and stiffness
- Relaxation of muscles
- Temporary relief (or relaxation) of muscle spasms
- Temporary relief of minor pain and stiffness associated with arthritis

The Electro-Light Therapy system is intended to be used alone or at the same time with legally marketed powered muscle stimulators, TENS units or Interferential Current Therapy when used with the transparent Electro-Light electrode.

12. Standards

12.1 Mandatory Standards

There are no mandatory standards for the type of device contained in this 510(k).

12.2 Consensus Standards

The Electro-Light Therapy is designed to comply with the following Consensus Standards:

STANDARD NO.	TITLE
IEC 60601-1 +A1, +A2	Medical Electrical Equipment- Part 1: General Requirements for Safety

13. Predicate Devices

510(k) Number	*Trade or Proprietary or Model Name*	*Manufacturer*	*Class*
K072256	HF 54 with Optional Hands-free operation	Hill Laboratories	2
K071445	Terraquant Mq2000 V.5 With The Tq-1 Tens	Medical Quant LTD.	2

13.1 Substantial Equivalence (SE) Rationale

13.1.1 Technology

The Electro-Light Therapy offers similar infrared therapy to the K072256 predicate device. The IR Light covered by K072256 allowed the operation of only one light head. The Electro-Light Therapy can support up to 4 light heads each with a similar intensity to the predicate K072256.

The significant difference between the Electro-Light Therapy device and the Terraquant Mq2000 V.5 With the Tq-1 Tens is that the predicate device K071445 is equipped with an on-board TENS stimulator. The Electro-Light Therapy device does not have a built-in TENS stimulator.

The Electro-Light Therapy device can shine its IR light through the optional transparent gel electrodes. In the case of the predicate K071445, the electrode is an annular gel electrode ring attached to the front of the IR applicator and light can shine through the middle of the electrode ring. The Electro-Light Therapy is intended be used with any legally marketed TENS, interferential, or powered muscle stimulator. The IR and visible light will pass through a clear gel electrode. The gel electrode was cleared under K072256. Like the predicate devices, the Electro-Light Therapy is intended to be used only by a qualified therapist.

Both the predicate devices and the new device are intended to be used on a cart.

13.1.2 Standards

The Electrical Safety of the predicate device is consistent with FDA guidance and international standards. The new device is in compliance to the same standards.

13.1.3 Materials

The materials used in construction of the device, including the patient contacting parts and the method of information display are similar to the predicate cleared under .

13.1.4 Measured Parameters

The measured parameters for the proposed Electro-Light Therapy are the similar to those displayed on the device cleared under K072256.

13.1.5 Risk Analysis

The primary risks were identified as:

- Temperatures in tissues above 45 °C
- Patient falling asleep during treatment

13.1.5.1 Temperatures in Tissues

From Measurement, it was shown that the maximum temperature was 45 °C there is no new safety issue when compared with the K072256 predicate.

13.1.5.2 Patient falling asleep during treatment

The operator's manual requires that the operator remain in the same area as the patient and must monitor the patient to ensure that the patient has not fallen asleep.

The primary difference between the new device and the predicate K072256 is that the predicate has a setting that allows continuous IR output whereas the new device has a maximum time setting of 99 minutes. This is not considered to be significant.

13.2 Conclusion

The proposed Electro-Light Therapy when used as directed in the operator's manual presents no new safety or effectiveness concerns and is Substantially Equivalent to the IR therapy hand-piece cleared under K072256. The Electro-Light Therapy also has same characteristics of combined electrotherapy and IR therapy as the K071445 predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Hill Laboratories
% Mr. Brady Aller
3 Bacton Hill Road
Frazer, PA 19355

Re: K090250
Trade/Device Name: Electro-Light Therapy
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: II
Product Code: ILY
Dated: February 2, 2010
Received: February 3, 2010

FEB 11 2010

Dear Mr. Aller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4: INDICATIONS FOR USE STATEMENT

Indications For Use statement

510(k) No.
If known _____

Device Name: Electro-Light Therapy

Indications For Use:

Electro-Light Therapy System is used to provide topical heating for:

- Temporary increases in local blood flow and circulation
- Temporary relief of minor muscle and joint aches
- Temporary relief of pain and stiffness
- Relaxation of muscles
- Temporary relief (or relaxation) of muscle spasms
- Temporary relief of minor pain and stiffness associated with arthritis

The Electro-Light Therapy system is intended to be used alone or at the same time with legally marketed powered muscle stimulators, TENS units or Interferential Current Therapy when used with the transparent Electro-Light electrode.

Prescription Use (Per 21 CFR 801 Subpart D) X AND/OR Over-The-Counter Use (Per 21 CFR 801 Subpart C) _____

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FOR M. MELKERS

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K090250